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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,334	05/12/2005	Jean-Max Huot	MART0890US	3598
24235 7590 12/04/2008 LEVINE & MANDELBAUM 222 Bloomingdale Road Suite 203 WHITE PLAINS, NY 10605				
EXAMINER				
BOUCHELLE, LAURA A				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
12/04/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,334

Applicant(s)

HUET, JEAN-MAX

Examiner

LAURA A. BOUCHELLE

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huet (EP 1116493) in view of MacGregor (US 4579120). Huet discloses an anti-stick device comprising a needle 17 having a bend, a needle holding panel F, a base panel C, a covering panel A, walls, E,B, the base panel and the needle holding panel having holes 15, 16 to receive the needle, the base panel having branches D, and the needle holding panel having lugs 9, 10. See Fig.1. The device functions in the same manner as applicant's invention. See Figs. 1-10.
3. Claim 1 differs from Huet in calling for the base panel and the needle holding panel to be curved. Macgregor teaches a device for anchoring a catheter on a patient's skin wherein the device is formed with a curve so that it can conform to the contours of the patient's body to stabilize the catheter and increase patient comfort (Col. 3, lines 45-46). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Huet to include a curved base and needle holding panel in the same manner as the device of MacGregor is curved so that they conform to the patient's body to increase stability of the needle and thus patient comfort.
4. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huet in view of MacGregor as applied to claim 1 above, and further in view of Knotek (US 5531704). Claim 2 differs from Huet in calling for the device to include a hard plastic material on the first pair of branches on the base panel. Knotek teaches a needle puncture protection device have a panel

configuration similar to that of Huet but further including a hard plastic portion 30 that maintains the needle in the safety position (Sol. 7, lines 9-15). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Huet to include a hard plastic portion as taught by Knotek that ensures that the needle stays within the safety enclosure to prevent accidental sticks.

Response to Arguments

5. Applicant's arguments filed 8/13/08 have been fully considered but they are not persuasive.
6. Applicant argues that MacGregor does not teach a solution to the problem of firmly maintaining an underskin chamber in place during implantation and withdrawal of a needle. The examiner believes that this feature is taught by Huet. The branches D of Huet remain on the skin as the lugs 9, 10 are pulled upwardly thereby removing the needle 17 from the insertion site. Therefore, Huet itself teaches a solution to the above stated problem. Refillable chambers may be inserted in the abdomen or the chest or other flat areas of the body, and in such a case, the device of Huet would hold the chamber in place during implantation and removal of the needle. The curvature of the device is not the only aspect of the invention that solves the problem. The problem is solved primarily by the outwardly extending branches.
7. The applicant argues that one of skill in the art would not look to MacGregor to modify Huet. The examiner disagrees. Both MacGregor and Huet are devices that contact the patient's body to secure an inserted member. MacGregor is relied upon to teach that it is known in the art to conform the body contacting surface of a medical device to the surface it is to be in contact

with to secure and immobilize the inserted device to increase patient comfort and prevent migration of the device.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
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